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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/625,644	07/26/2000	Saumil N. Merchant	00633-025001	8315
26161	7590	08/11/2004	EXAMINER	
FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110			ISABELLA, DAVID J	
			ART UNIT	PAPER NUMBER
			3738	

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/625,644
Filing Date: July 26, 2000
Appellant(s): MERCHANT ET AL.

Faustino A. Lichauco
For Appellant

EXAMINER'S ANSWER

MAILED
AUG 12 2004
GROUP 3700

This is in response to the appeal brief filed July 16, 2004.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

The brief does not contain a statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief. Therefore, it is presumed that there are none. The Board, however, may exercise its discretion to require an explicit statement as to the existence of any related appeals and interferences.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is incorrect.

The amendment after final rejection filed on 1/28/03 has been entered.

The terminal disclaimer as filed on 10/28/2002 has been approved.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(7) *Grouping of Claims*

The rejection of claims 1-26 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

5,480,433	Nadol, Jr.	1-1996
5,480,433	Nadol, Jr	10-1994

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

Claims 1,3-20,22-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Nadol (5356430 or 5480433).

Nadol discloses an implant for implantation in a middle-ear chamber, said implant comprising: a pliant membrane formed into a balloon, said balloon configured to fit within said middle-ear chamber and to contact an eardrum, said pliant membrane forming a balloon to permit said eardrum to respond to incident acoustic waves to an extent that permits the perception of sound. (See column 1, line 50; column 2, lines 54-56; column 3, lines 1-5; column 4, lines 15-17; and column 6, lines 61-67). Column 2, lines 51-58, Nadol discloses that the synthetic bubble 10 is adapted for positioning between the eardrum and round window to displace fluid therebetween. By maintaining a reservoir of gas (ie equivalent volume) in compressible form located proximate to the

round window, the round window is assured a degree of compliance comparable to that of a normal ear.

Claim Rejections - 35 USC § 103

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nadol (5356430 or 5480433).

It is not clear what value is defined by an acoustic impedance corresponding to an equivalent volume of at least 70% of the physical volume of the balloon. However, Nadol discloses, column 5, lines 45-65 various computer models to simulate the composition and pressure of gas inside the balloon based on different initially inflation conditions. One model the balloon was initially full of atmospheric air and another model the balloon was entirely filled with SF₆. Moreover, column 6, lines 24-30, the balloon is filled with several normal gases as a substantial fraction of the initial fill mixture, e.g. fifty to eighty percent. In each model the equivalent volume is at least 70% of the physical volume of the balloon.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nadol (5356430 or 5480433).

Nadol, column 7, lines 3-6 and 20-25 teaches that the balloon is sized to allow for placement in the hypotympanic cavity and may take diverse shapes and be implemented with a variety of materials to allow normal displacement of the round window. To use

more than one balloon is a mere multiplicity of elements that would perform the same function as one balloon.

(11) Response to Argument

In response to applicant's argument that the references fail to show certain features of appellant's invention, it is noted that the features upon which appellant relies (i.e., implanting a balloon having an equivalent volume of at least 70% of the physical volume can restore hearing in a patient) are not recited in the rejected claim(s).

Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Claim 1 and claim 22, requires an implant to have an equivalent volume to permit said eardrum to respond to incident acoustic waves to an extent that *permits the perception of sound* (italics added). Appellant argues and supplied a declaration in support of the argument, that in clinical trials the balloon with an impedance that matched the tympanum and round window did not function consistently to significantly enhance acoustic transmission between the eardrum and the middle ear. These arguments are not commensurate with the scope of the claimed invention. Claims 1 and 22 requires a balloon, which may be completely filled (ie 100% as disclosed in Nadol) and therefor have an equivalent volume equaled to the physical volume wherein, when the implant is placed in the middle-ear chamber to contact an eardrum, the implant permits the eardrum to respond to incident acoustic waves that permits the perception of sound. There is no language in the claims that require the

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acoustic transmission between the eardrum and the middle ear be significantly enhance and/or provide sufficient acoustic energy to the middle ear to enhance a patient's perception of sound. Clearly the implant of Nadol (5,536,430 and 5,480,433) performs the simple function of responding to incident acoustic waves to an extent that permits the perception of sound. The level of sound does not have to be enhanced or at a level to restore hearing in a patient, the device need only to permit the perception of sound. For the above reasons, it is believed that the rejections should be sustained.

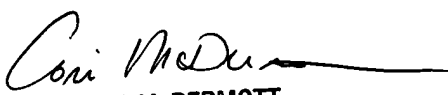
Respectfully submitted,

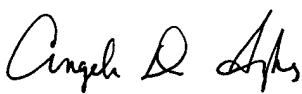
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July 26, 2004

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